

## UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE United States Patent and Trademark Office Address: COMMISSIONER FOR PATENTS P.O. Box 1450 Alexandria, Virginia 22313-1450 www.uspto.gov

# NOTICE OF ALLOWANCE AND FEE(S) DUE

21710 "

7590

08/26/2003

BROWN, RUDNICK, BERLACK & ISRAELS, LLP. BOX 12, 18TH FLOOR

ONE FINANCIAL CENTER BOSTON, MA 02111 EXAMINER

CHISM, BILLY D

ART UNIT

CLASS-SUBCLASS

1654

514-019000

7886

DATE MAILED: 08/26/2003

20784/4

APPLICATION NO. 09/745,776

FILING DATE 12/22/2000 FIRST NAMED INVENTOR
Hans-Ulrich Demuth

ATTORNEY DOCKET NO.

CONFIRMATION NO.

TITLE OF INVENTION: PRODRUGS OF DP IV-INHIBITORS

APPLN. TYPE	SMALL ENTITY	ISSUE FEE	PUBLICATION FEE	TOTAL FEE(S) DUE	DATE DUE
nonprovisional	NO	\$1300	\$300	\$1600	11/26/2003

THE APPLICATION IDENTIFIED ABOVE HAS BEEN EXAMINED AND IS ALLOWED FOR ISSUANCE AS A PATENT. PROSECUTION ON THE MERITS IS CLOSED. THIS NOTICE OF ALLOWANCE IS NOT A GRANT OF PATENT RIGHTS. THIS APPLICATION IS SUBJECT TO WITHDRAWAL FROM ISSUE AT THE INITIATIVE OF THE OFFICE OR UPON PETITION BY THE APPLICANT. SEE 37 CFR 1.313 AND MPEP 1308.

THE ISSUE FEE AND PUBLICATION FEE (IF REQUIRED) MUST BE PAID WITHIN THREE MONTHS FROM THE MAILING DATE OF THIS NOTICE OR THIS APPLICATION SHALL BE REGARDED AS ABANDONED. THIS STATUTORY PERIOD CANNOT BE EXTENDED. SEE 35 U.S.C. 151. THE ISSUE FEE DUE INDICATED ABOVE REFLECTS A CREDIT FOR ANY PREVIOUSLY PAID ISSUE FEE APPLIED IN THIS APPLICATION. THE PTOL-85B (OR AN EQUIVALENT) MUST BE RETURNED WITHIN THIS PERIOD EVEN IF NO FEE IS DUE OR THE APPLICATION WILL BE REGARDED AS ABANDONED.

#### HOW TO REPLY TO THIS NOTICE:

I. Review the SMALL ENTITY status shown above.

If the SMALL ENTITY is shown as YES, verify your current SMALL ENTITY status:

A. If the status is the same, pay the TOTAL FEE(S) DUE shown above.

B. If the status is changed, pay the PUBLICATION FEE (if required) and twice the amount of the ISSUE FEE shown above and notify the United States Patent and Trademark Office of the change in status, or

If the SMALL ENTITY is shown as NO:

- A. Pay TOTAL FEE(S) DUE shown above, or
- B. If applicant claimed SMALL ENTITY status before, or is now claiming SMALL ENTITY status, check the box below and enclose the PUBLICATION FEE and 1/2 the ISSUE FEE shown above.
- Applicant claims SMALL ENTITY status. See 37 CFR 1.27.
- II. PART B FEE(S) TRANSMITTAL should be completed and returned to the United States Patent and Trademark Office (USPTO) with your ISSUE FEE and PUBLICATION FEE (if required). Even if the fee(s) have already been paid, Part B Fee(s) Transmittal should be completed and returned. If you are charging the fee(s) to your deposit account, section "4b" of Part B Fee(s) Transmittal should be completed and an extra copy of the form should be submitted.
- III. All communications regarding this application must give the application number. Please direct all communications prior to issuance to Mail Stop ISSUE FEE unless advised to the contrary.

IMPORTANT REMINDER: Utility patents issuing on applications filed on or after Dec. 12, 1980 may require payment of maintenance fees. It is patentee's responsibility to ensure timely payment of maintenance fees when due.

#### PART B - FEE(S) TRANSMITTAL

# Complete and send this form, together with applicable fee(s), to: Mail Mail Stop ISSUE FEE

**Commissioner for Patents** Alexandria, Virginia 22313-1450

or Fax (703) 746-4000

INSTRUCTIONS: This form should be used for transmitting the ISSUE FEE and PUBLICATION FEE (if required). Blocks 1 through 4 should be completed where appropriate. All further correspondence including the Patent, advance orders and notification of maintenance fees will be mailed to the current correspondence address as indicated unless corrected below or directed otherwise in Block 1, by (a) specifying a new correspondence address; and/or (b) indicating a separate "FEE ADDRESS" for maintenance fee notifications.

CURRENT CORRESPONDENCE ADDRESS (Note: Legibly mark-up with any corrections or use Block 1)

21710

08/26/2003

BROWN, RUDNICK, BERLACK & ISRAELS, LLP. BOX IP, 18TH FLOOR ONE FINANCIAL CENTER **BOSTON, MA 02111** 

Note: A certificate of mailing can only be used for domestic mailings of the Fee(s) Transmittal. This certificate cannot be used for any other accompanying papers. Each additional paper, such as an assignment or formal drawing, must have its own certificate of mailing or transmission.

Certificate of Mailing or Transmission

I hereby certify that this Fee(s) Transmittal is being deposited with the United States Postal Service with sufficient postage for first class mail in an envelope addressed to the Mail Stop ISSUE FEE address above, or being facsimile transmitted to the USPTO, on the date indicated below.

(Depositor's name) (Signature (Date)

APPLICATION NO. FILING DATE FIRST NAMED INVENTOR ATTORNEY DOCKET NO. CONFIRMATION NO. 09/745,776 12/22/2000 Hans-Ulrich Demuth 20784/4

TITLE OF INVENTION: PRODRUGS OF DP IV-INHIBITORS

APPLN. TYPE	SMALL ENTITY	ISSUE FEE		PUBLICATION FEE	TOTAL FEE(S) DUE	DATE DUE	
nonprovisional	NO	\$1300		\$300	\$1600	11/26/2003	
EXAMINER		ART UNIT		CLASS-SUBCLASS	] .		
CHISM, BILLY D 16.		1654	4 514-019000		• •	•	
<ol> <li>Change of correspondence address or indication of "Fee Address" (37 CFR 1.363).</li> </ol>				2. For printing on the patent front page, list (1) the names of up to 3 registered patent attorneys or 1			
☐ Change of correspondence address (or Change of Correspondence Address form PTO/SB/122) attached.			agents OR, alternatively, (2) the name of a single firm (having as a member a registered attorney or 2				
☐ "Fee Address" indication (or "Fee Address" Indication form PTO/SB/47; Rev 03-02 or more recent) attached. Use of a Customer Number is required.			agent) and the names of up to 2 registered patent attorneys or agents. If no name is listed, no name will be printed.			<del></del>	

#### 3. ASSIGNEE NAME AND RESIDENCE DATA TO BE PRINTED ON THE PATENT (print or type)

PLEASE NOTE: Unless an assignee is identified below, no assignee data will appear on the patent. Inclusion of assignee data is only appropriate when an assignment has

(A) NAME OF ASSIGNEE	• • • • • • • • • • • • • • • • • • • •	g submitted under separate cover. Completion of this form is NOT a substitute for filing an assignment.  (B) RESIDENCE: (CITY and STATE OR COUNTRY)			
Please check the appropriate assignee category	y or categories (will not be printed on the patent);	□ individual	corporation or other private group entity	☐ government	
4a. The following fee(s) are enclosed:	4b. Payment of Fee(s):	•			
☐ Issue Fee	☐ A check in the amo	ount of the fee(s)	is enclosed.		
☐ Publication Fee	☐ Payment by credit	card. Form PTO-	2038 is attached.		
Advance Order - # of Copies	☐ The Director is he Deposit Account Nur	reby authorized	by charge the required fee(s), or credit any (enclose an extra copy of this	overpayment, to form).	
	ssue Fee and Publication Fee (if any) or to re-apply	any previously p	oaid issue fee to the application identified about	ve.	
other than the applicant; a registered attor interest as shown by the records of the Unite					
application. Confidentiality is governed by 3 estimated to take 12 minutes to complete, it completed application form to the USPTO case. Any comments on the amount of t suggestions for reducing this burden, shoul	by 37 CFR 1.311. The information is required to ich is to file (and by the USPTO to process) an S U.S.C. 122 and 37 CFR 1.14. This collection is including gathering, preparing, and submitting the . Time will vary depending upon the individual ime you require to complete this form and/or d be sent to the Chief Information Officer, U.S. partment of Commerce, Alexandria, Virginia COMPLETED FORMS TO THIS ADDRESS. andria, Virginia 22313-1450.				
Under the Paperwork Reduction Act of I collection of information unless it displays a	1995, no persons are required to respond to a valid OMB control number.				



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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.	
09/745,776	12/22/2000 Hans-Ulrich Demuth		20784/4	7886	
21710	21710 7590 08/26/2003		EXAMINER		
BROWN, RUDNICK, BERLACK & ISRAELS, LLP.			CHISM, BILLY D		
BOX IP, 18TH ONE FINANCI			ART UNIT	PAPER NUMBER	
BOSTON, MA	02111		1654	<del></del>	
			DATE MAILED: 08/26/200	3	

# Determination of Patent Term Adjustment under 35 U.S.C. 154 (b)

(application filed on or after May 29, 2000)

The Patent Term Adjustment to date is 363 day(s). If the issue fee is paid on the date that is three months after the mailing date of this notice and the patent issues on the Tuesday before the date that is 28 weeks (six and a half months) after the mailing date of this notice, the Patent Term Adjustment will be 363 day(s).

If a Continued Prosecution Application (CPA) was filed in the above-identified application, the filing date that determines Patent Term Adjustment is the filing date of the most recent CPA.

Applicant will be able to obtain more detailed information by accessing the Patent Application Information Retrieval (PAIR) system (http://pair.uspto.gov).

Any questions regarding the Patent Term Extension or Adjustment determination should be directed to the Office of Patent Legal Administration at (703) 305-1383. Questions relating to issue and publication fee payments should be directed to the Customer Service Center of the Office of Patent Publication at (703) 305-8283.



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21710	21710 7590 08/26/2003		EXAMINER		
BROWN, RUDNICK, BERLACK & ISRAELS, LLP.		CHISM, BILLY D			
BOX IP, 18TH F	LOOR				
ONE FINANCIA			ART UNIT	PAPER NUMBER	
BOSTON, MA 02	2111		1654		
			DATE MAILED: 08/26/2003	3	

Notice of Fee Increase on October 1, 2003

If a reply to a "Notice of Allowance and Fee(s) Due" is filed in the Office on or after October 1, 2003, then the amount due will be higher than that set forth in the "Notice of Allowance and Fee(s) Due" since there will be an increase in fees effective on October 1, 2003. See Revision of Patent Fees for Fiscal Year 2004; Final Rule, 68 Fed. Reg. 41532, 41533, 41534 (July 14, 2003).

The current fee schedule is accessible from (http://www.uspto.gov/main/howtofees.htm).

If the fee paid is the amount shown on the "Notice of Allowance and Fee(s) Due" but not the correct amount in view of the fee increase, a "Notice of Pay Balance of Issue Fee" will be mailed to applicant. In order to avoid processing delays associated with mailing of a "Notice of Pay Balance of Issue Fee," if the response to the Notice of Allowance is to be filed on or after October 1, 2003 (or mailed with a certificate of mailing on or after October 1, 2003), the issue fee paid should be the fee that is required at the time the fee is paid. If the issue fee was previously paid, and the response to the "Notice of Allowance and Fee(s) Due" includes a request to apply a previously-paid issue fee to the issue fee now due, then the difference between the issue fee amount at the time the response is filed and the previously-paid issue fee should be paid. See Manual of Patent Examining Procedure, Section 1308.01 (Eighth Edition, August 2001).

Effective October 1, 2003, 37 CFR 1.18 is amended by revising paragraphs (a) through (c) to read as set forth below.

Section 1.18 Patent post allowance (including issue) fees.

(a) Issue fee for issuing each original or reissue patent, except a design or plant patent:

By a small entity (Sec. 1.27(a))......\$665.00 By other than a small entity...... \$1,330.00

(b) Issue fee for issuing a design patent:

By a small entity (Sec. 1.27(a)).....\$240.00 By other than a small entity......\$480.00

(c) Issue fee for issuing a plant patent:

By a small entity (Sec. 1.27(a))......\$320.00

By other than a small entity......\$640.00

Questions relating to issue and publication fee payments should be directed to the Customer Service Center of the Office of Patent Publication at (703) 305-8283.

	Application No	0.	Applicant(s)		
	09/745,776		DEMUTH ET AL.		
Notice of Allowability	Examiner		Art Unit	Γ	
	B. Dell Chism		1654		
The MAILING DATE of this communication appe All claims being allowable, PROSECUTION ON THE MERITS IS herewith (or previously mailed), a Notice of Allowance (PTOL-85) NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RI of the Office or upon petition by the applicant. See 37 CFR 1.313	(OR REMAINS) or other appropr IGHTS. This app	CLOSED in this app riate communication plication is subject to	olication. If not include will be mailed in due	ed course, <b>THIS</b>	
<ol> <li>This communication is responsive to Paper No. 15 filed 27</li> <li>The allowed claim(s) is/are 1,5,7 and 13-16.</li> <li>The drawings filed on are accepted by the Examine.</li> <li>Acknowledgment is made of a claim for foreign priority und a)  All b)  Some* c) None of the:         <ol> <li>Certified copies of the priority documents have</li> <li>Copies of the certified copies of the priority documents have</li> </ol> </li> </ol>	er. der 35 U.S.C. § 1 e been received. e been received i	in Application No		ition from the	
International Bureau (PCT Rule 17.2(a)).  * Certified copies not received:  5.  Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).  (a)  The translation of the foreign language provisional application has been received.  6.  Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.  Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted					
below. Failure to timely comply will result in ABANDONMENT of to 7.   A SUBSTITUTE OATH OR DECLARATION must be subminformal patent application (PTO-152) which gives reasonable to timely comply will result in ABANDONMENT of the patent application of the patent application (PTO-152) which gives reasonable to timely comply will result in ABANDONMENT of the patent application of the patent application and the patent application application and the patent application application application and the patent application and the patent application application application and the patent application application application application and the patent application application application application and the patent application applica	nitted. Note the a	attached EXAMINER'	'S AMENDMENT or N		
<ul> <li>8.  CORRECTED DRAWINGS must be submitted.</li> <li>(a)  including changes required by the Notice of Draftspers</li> <li>1)  hereto or 2)  to Paper No</li> <li>(b)  including changes required by the proposed drawing or</li> <li>(c)  including changes required by the attached Examiner's</li> </ul>	correction filed _	, which has be	en approved by the E		
Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet.					
9.   DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.					
Attachment(s)					
<ul> <li>1 Notice of References Cited (PTO-892)</li> <li>3 Notice of Draftperson's Patent Drawing Review (PTO-948)</li> <li>5 Information Disclosure Statements (PTO-1449), Paper No</li></ul>	4[ 6[ 8[	☐ Interview Summa ☑ Examiner's Amen	I Patent Application (I ry (PTO-413), Paper Idment/Comment ment of Reasons for A	No	
				·	

Application/Control Number: 09/745,776

Art Unit: 1654

### **EXAMINER'S AMENDMENT**

1. An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it MUST be submitted no later than the payment of the issue fee.

Authorization for this examiner's amendment was given in a telephone interview with Tom Saunders and John Serio on 21 August 2003.

2. The application has been amended as follows:

Claim 2 is canceled.

Claim 3 is canceled.

Claim 4 is canceled.

Claim 6 is canceled.

Claim 7, line 2, the word "a" has been deleted and replaced with --the--.

Claim 7, line 2, the phrase "that is an of inhibitors of dipeptidyl peptidase IV wherein said" has been deleted and replaced with --of claim 1--.

Claim 7, line 3, the phrase "pharmaceutical composition comprises at least one prodrug compound" has been deleted.

Claim 7, line 4, the phrase "with pharmaceutical" has been deleted and replaced with --with one or more pharmaceutical--

Claim 8 is canceled.

Claim 9 is canceled.

Claim 10 is canceled.

Art Unit: 1654

Claim 11 is canceled.

Claim 12 is canceled.

Claim 14, line 1, the word "compounds" has been deleted and replaced with --compound-

Any inquiry concerning this communication or earlier communications from the examiner should be directed to B. Dell Chism whose telephone number is 703-306-5815. The examiner can normally be reached on 7:30 AM - 4:30 PM, Monday through Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brenda Brumback can be reached on 703-306-3220. The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-4242 for regular communications and 703-308-4242 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1235.

B. Dell Chism

25 August 2003

CHRISTOPHER R. IAIE PRIMARY EXAMINER